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Effectiveness of adding magnesium sulfate to bupivacaine in ultrasound guided serratus anterior plane block in patients undergoing modified radical mastectomy

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ABSTRACT

Background: This research work investigated the effect of magnesium sulfate added to bupivacaine in serratus anterior block in cases of modified radical mastectomy.

Patients and method: A total of 80 female patients of ASA I and II were randomly assigned into two equal groups depending on the adjuvant added to bupivacaine. B group: patients received 20 ml 0.5% bupivacaine with 5 ml 0.9% normal saline. BM group: patients received 20 ml 0.5% bupivacaine+150 mg magnesium sulfate in 0.9% normal saline with a total volume of 25 ml in both groups. Primary aim was to test the effect of magnesium sulfate when added to bupivacaine on pain intensity. Secondary targets were to detect the haemodynamics, safety and any side effects of magnesium sulfate.

Results: Visual analogue scale measurement showed statistical significant decrease after 4 hours till 24 hours postoperatively in BM group more than in B group. Mean time to first rescue analgesia in BM group was 11.73 ± 1.91 hours versus 8.13 ± 1.38 hours in B group with P value < 0.001. The mean total dose of nalbuphine used was statistically significantly decreased in BM group, as it was 15.50 ± 3.89 mg in B group and 9.63 ± 4.44 mg in BM group with P value < 0.001. Occurrence of complications in both groups showed insignificant statistical difference.

Conclusions: Magnesium sulfate with bupivacaine in serratus anterior plane block produced prolonged analgesia postoperatively without significant haemodynamic instability with significant decline in the total dose of rescue analgesic with minimal side effects.

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1 Introduction

About 30% of female patients undergoing breast surgeries are doing modified radical mastectomy (MRM), commonly done under general anesthesia. [1] Most of the patients complain of postoperative pain of varying degrees [2,3]. Acute pain postoperatively is a major cause for the occurrence of the syndrome of chronic pain which includes paraesthesia, phantom breast pain and intercostobrachial neuralgia, and these types of pain occur in about 25–40% of the patient [4,5].

For perioperative pain management, different regional anaesthetic procedures are available and can subsequently decrease the use of opiates and so reducing their common adverse effects. Paravertebral block, thoracic epidural block and local wound infiltration are good choice of these regional techniques. [6,7]

Serratus anterior plane block (SAPB) is recently introduced analgesic technique for female patients planned for breast surgeries. [8,9] The target plane of SAPB is between the serratus anterior and the latissimus dorsi muscles. [10] Its analgesic effect is produced by blocking lateral branches of thoracic intercostal nerves II, III and VI. SAPB under sonography, its anatomy is easy to be identified and reached, and the expected complications related to the pleura and central neuraxial structures can be avoided. [11,12] Different drugs as adjuvant to local anaesthetic may be used such as fentanyl, morphine and dexmedetomidine to improve the quality of regional blocks in breast surgeries, but these adjuvants may be associated with many adverse effects as nausea, vomiting and hypotension. [13–15]

Magnesium sulfate is one of these adjuvants and has a role to improve the analgesic effect of the block. Its mechanism of action occurs through competition with one of excitatory amino acid receptors, which is N-methyl-D-aspartate receptors antagonist (NMDA). In response to painful stimuli, excitatory neurotransmitters stimulate these receptors, such as glutamate and aspartate. [16–18] Magnesium blocks the influx of calcium into the cells, which occurs because of NMDA receptors activation. With calcium influx, a cascade of specific changes to the central nervous system occur, including wind-up pain, hyperalgesia and prolonged potentiating action, which affect the duration and severity of postoperative pain. Therefore, magnesium

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prevents these sequences of reactions and leads to the reduction of postoperative pain. [19,20]

This work was conducted to investigate the effect of combination of magnesium sulfate to bupivacaine versus bupivacaine alone in ultrasound (US)-guided SAPB for MRM. The primary aim was to assess the intensity of postoperative pain by visual analogue scale (VAS) and the secondary aims were to detect the haemodynamic effects, safety and adverse effects of magnesium sulfate when added to bupivacaine.

2 Patients and methods

Ethical approval from Institutional Review Board at Alexandria Faculty of Medicine was taken for this prospective, randomized, blinded study. Informed consents were taken from all female patients included in this work. Registration at ClinicalTrials.gov was done before patient enrollment in the study, with registration ID: NCT04429893.

This work was carried on a period between January and September 2022 on 80 female participants prepared for unilateral MRM, aged between 20 and 65 years, of ASA Status I and II.

As shown in the flowchart of the studied groups in Figure 1, patients were randomly assigned into two groups (40 participants in each group). Randomization through a computer program was used and numbers were kept in a sealed opaque envelope. Patients in B group received 20 ml 0.5% bupivacaine+5 ml 0.9% normal saline, while patients in BM group received 20 ml 0.5% bupivacaine+150 mg magnesium sulfate in 0.9% normal saline with a total volume of 25 ml in both groups.

The study's exclusion criteria included patient refusal, bilateral breast surgery, coagulation disorders, allergy to any of the drugs used, body mass index more than 35, pre-existing neurological deficits, and renal, liver, respiratory or cardiac diseases.

Preoperative patients assessment was done by proper history taking and clinical examination, and during the preanesthetic evaluation, patients' education about pain measurement was done on VAS on 11-point scale as 0 = no pain and 10 = worst severe pain.

In the operating room, the patients were connected to the standard monitoring system for the measurement of mean arterial blood pressure (MABP), heart rate (HR), and O_2 saturation. Insertion of intravenous line with 22-gauge cannula was done. Sedation with IV midazolam 0.05–0.1 mg/kg was used to alleviate anxiety. US-guided SAPB was done before starting the induction of general anaesthesia while continuous O_2 through nasal cannula was given.

The patient was positioned on the lateral side with the side of the incision upwards with arm abduction. Sterilization of the area of the block was done with 10% betadine.

A linear US probe (10–13 MHz) was positioned in a sagittal plane on the area of mid-clavicle. Counting of the ribs till reaching the fifth rib was done in the mid-axillary line. Then, the identification of the muscles

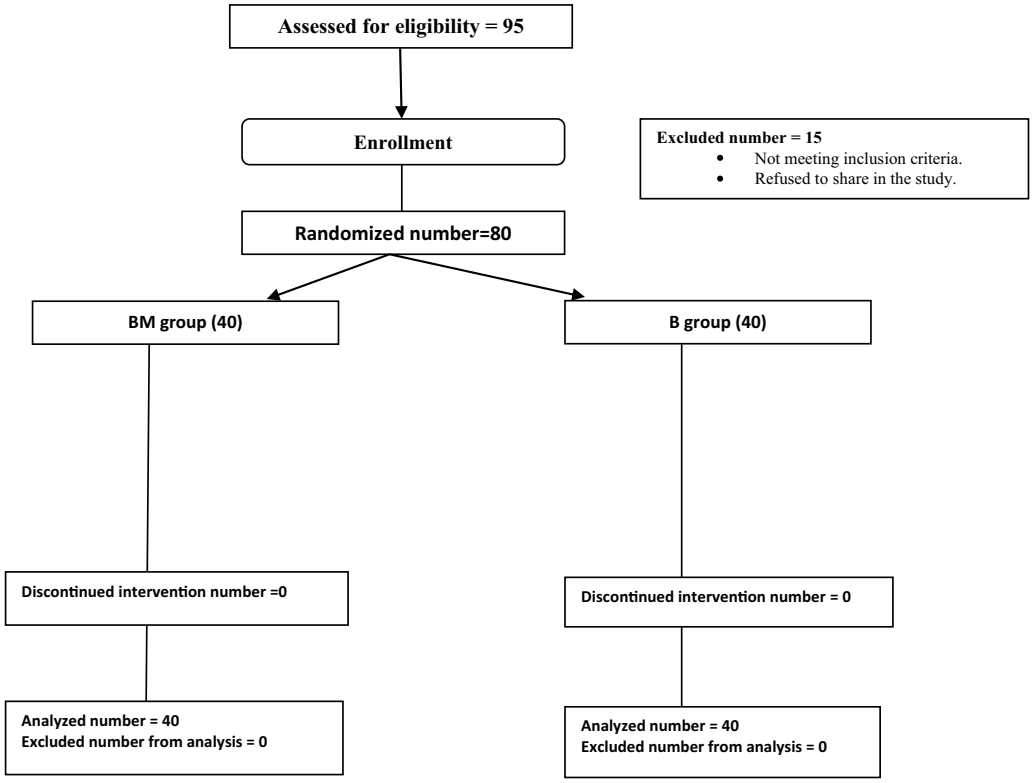

Figure 1. Flow diagram of involved patients in the study.

lying over the fifth rib was done, and these muscles include latissimus dorsi, teres major and serratus anterior muscle. Advancement of the needle was progressed from posterior toward antero-caudal direction till reaching superficial to serratus anterior muscle. Then, injection of the prepared drugs was done under continuous US guidance. Pinprick test was examined within 20 minutes after the block, and if its recognition was delayed for more than 20 minutes in the dermatomes from T2 to T9, failure of the block was considered and exclusion of these patients from the study was done. [21] Anaesthesiologist who did not share in patients' management prepared the drugs. The study is considered double blinded as the participants and the staff personnel shared in the techniques and data collection was blinded to the groups' allocation.

Standardized anaesthesia protocol was followed in both groups; first, pre-oxygenation for 3 minutes and then induction was done with intravenous fentanyl (1–1.5 µg/kg), propofol (1.5–2 mg/kg) and then cis-atracurium (0.1 mg/kg) as muscle relaxant was given for endotracheal intubation facilitation. Dräger Fabius plus ventilator was used to control the ventilation with the maintenance of end tidal CO_2 between 32 and 35 mmHg. Anaesthesia was maintained with 1.5–2% isoflurane in 100% O_2 and intermittent boluses of cisatracurium 0.03 mg/kg. Fentanyl 0.5 µg/kg was given if HR or MAP increased more than 20% from the basal readings.

After the completion of the surgical procedure, reversal of neuromuscular blockade was done with neostigmine 0.04 mg/kg and atropine 0.01 mg/kg, and after complete return of consciousness, endotracheal extubation was done. After complete recovery, the patients were transferred to post-anaesthesia care unit where monitoring for 24 hours after surgery occurred. Rescue analgesia with nalbuphine Hcl 0.05 mg/kg IV was used when VAS score at rest was >3 or on patient request.

Haemodynamic changes were continuously assessed and recorded: preoperative, after block, then every 20 minutes intraoperatively and then every 4 hours till 24 hours postoperatively.

Postoperative pain measurement by VAS score was assessed at rest and with the movement of the shoulder at 30 minutes and then at 2, 4, 6, 12 and 24 hours. Timing for first rescue analgesic requirement was measured and the total dose of nalbuphine requirement was recorded.

Postoperative nausea and vomiting (PONV) in the first 24 hour post-surgery was evaluated on a 4- point scale system (0 = no PONV, 1 = mild nausea with no vomiting, 2 = severe nausea with one episode of vomiting, 3 = vomiting ≥2 episodes). Ondansetron 4 mg as antiemetic was given if the score of PONV became more than 1.

Occurrence of any complications or adverse effects up to 24 hours after the surgery such as hypotension, respiratory depression and haematoma at the site of injection was recorded. All these effects were assessed at 2, 4, 8, 16 and 24 hours postoperatively.

Patient satisfaction with pain management was assessed 24 hours after surgery using a 5-point Likert scale (1 = very unsatisfied, 2 = unsatisfied, 3 = unsure, 4 = satisfied and 5 = very satisfied).

2.1 Statistical analysis

Sample size was estimated using the pain intensity by VAS as the primary endpoint based on previous research studies [2,5]. Sample size was calculated using the statistical software Med Calc. The minimum accepted sample size to reject the null hypothesis with area under ROC curve as 0.80 with alpha error of 0.05 and the power of the study as 90% was 36 patients in each group. Therefore, 80 patients as total number were taken to avoid any dropouts or block failure.

After collection of the raw data, statistical analysis was done using software of Statistical Package for Social Sciences (SPSS/version 24). A 5% level was used as the cutoff value for statistical significance.

Quantitative variables were presented as arithmetic mean ± standard deviation or median. Student's *t*-test was used for comparing independent quantitative normally distributed variables. Categorized parameters were reported as numbers and percentages. The association between the two categorized variables was tested by chi-squared (χ^2) test.

3 Results

A total of 95 patients were initially enrolled in the research study, and then 15 of them did not meet the inclusion criteria or refused to participate and hence they were excluded. Therefore, the final sample size was 80 patients in both groups (Figure 1). No statistical difference was detected between both groups as regard the basic data (age, ASA status, BMI) or duration of surgery as shown in Table 1.

HR and MABP measurements revealed no statistical difference between both groups at preoperative baseline reading and immediately after the block. After that, both decreased in BM group in comparison to B group all through other measurement times with statistical difference (P value ≤ 0.05) except at 8, 20 and 24 hours postoperative; no statistical difference was found as regard MAP and at 20 and 24 hours postoperative as regard HR as shown in Figures 2 and 3. Oxygen saturation measurements showed no statistical difference all through the measurement times as shown in Figure 4.

As regard postoperative pain scores as shown in Table 2, VAS at rest was statistically significantly lower in BM group in comparison to B group after fourth hour

Table 1. Patients' data and duration of surgery.

	B group		BM group		P value
Age (in years)					
Range	22–62		21–61		0.128 N.S.
Mean ± SD	47.28 ± 9.95		44.70 ± 10.17		
ASA	**No**	**%**	**No**	**%**	0.253 N.S.
I	24	60.0	21	52.5	
II	16	40.0	19	47.5	
BMI					
Range	21.1–33.2		21.1–34.2		0.128 N.S.
Mean ± SD	27.53 ± 3.03		28.47 ± 4.20		
Duration of surgery (in minutes)					
Range	70–80		70–80		0.300 N.S.
Mean ± SD	75.88 ± 4.22		75.38 ± 4.29		

N.S.: Not significant
Data are presented as range, mean ± SD or No. (%)

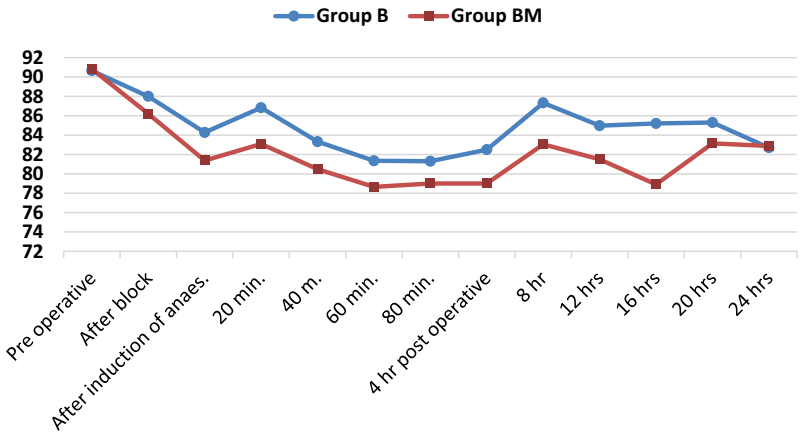

Figure 2. HR changes in both groups at different measurement times.

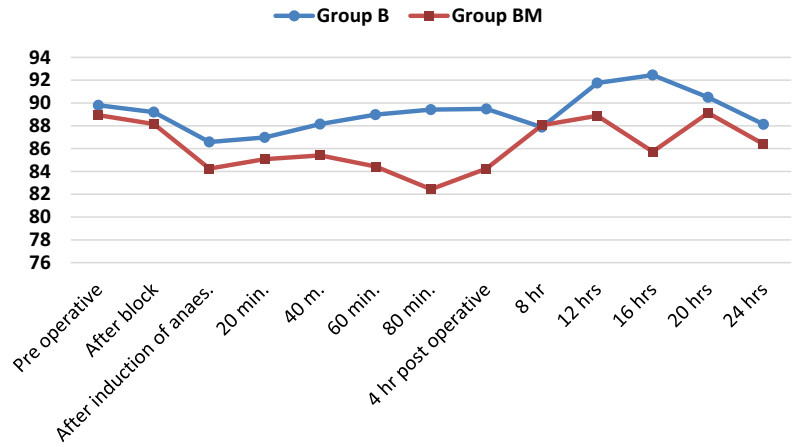

Figure 3. MAP changes in both groups at different measurement times.

postoperative until 24 hours postoperative. VAS with movement of shoulder showed statistically significantly lower pain score in BM group than in B group starting from the second hour postoperative till 24 hours.

Regarding time to first rescue analgesia required postoperatively as shown in Table 3, there was a statistically significantly longer latency period before starting the analgesia regimen in BM group more than in B group, with significant increase in the total dose of nalbuphine given for patients in B group more than in BM group (P value = 0.001).

As regard PONV, statistical significant difference between both groups was found as 18 patients in BM group complained from attacks of PONV compared to 26 patients in B group (P value 0.021). Patient satisfaction after surgery reported statistical difference between both groups as 45% of patients in BM group were satisfied after surgery in comparison to 25% in B group (P value 0.001). Regarding postoperative side effects, no statistical significance was detected between both groups (Table 4).

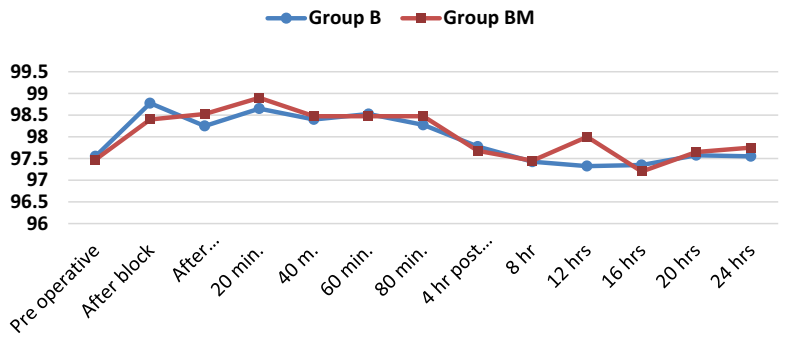

Figure 4. Oxygen saturation changes in both groups at different measurement times.

Table 2. VAS at rest and with movement at different postoperative times.

	B group		BM group		P value	
	At rest	With movement	At rest	With movement		
Timing postoperative	Median(Range)		Median(Range)		At rest	With movement
At 30min	1.0(0–2)	2.0(1–3)	1.0(0–2)	2.0(1–3)	0.500	0.342
At 2h	1.0(1–2)	3.0(2–3)	1.0(1–2)	2.0(1–3)	0.500	0.005*
At 4h	2.0(1–3)	2.0(2–3)	1.0(1–2)	2.0(1–3)	0.002*	0.017*
At 8h	2.5(1–4)	3.0(2–5)	2.0(1–3)	2.0(1–3)	0.049*	0.001*
At 12h	3.0(2–5)	4.0(2–6)	2.5(1–4)	3.5(1–5)	0.003*	0.009*
At 24 h	3.0(1–5)	4.0(2–6)	3.0(1–4)	3.0(1–5)	0.030*	0.001*

* P ≤ 0.05 is significant.

Table 3. Timing for the first rescue analgesia and total dose of nalbuphine in both groups.

	B group	BM group	P
Time till the first rescue analgesia in h			
Range	6–10	9–15	0.001*
Mean± SD	8.13±1.38	11.73±1.91	
Total dose of nalbuphine in mg			
Range	10–20	5–15	0.001*
Mean± SD	15.50±3.89	9.63±4.44	

Data are expressed as range – mean ± SD
* P ≤ 0.05 is significant.

4 Discussion

SAPB is easy to learn and perform, and it is relatively safe with minimal complications. [22] Blanco et al. [8] in their study on SAPB concluded a low vascularity in this target plane and so less absorption of local anesthetic drugs with decreased level of toxicity and so there was a reliable and widespread of the block. Diéguez [23] and Ohgoshi [24] and their colleagues reported that SAPB was effective and safe for postoperative analgesia in patients undergoing breast and axillary surgeries.

From the results of this research work, we found that magnesium sulfate as adjuvant to bupivacaine in SAPB guided by US improved postoperative pain scores and reduced postoperative analgesic requirements with minimal side effects.

In agreement with our study, Kanwar MS et al. [2] examined magnesium sulfate as an adjunct to bupivacaine in Pecs block under US guidance on 40 females of ASA I and II who underwent MRM with axillary dissection. In (LA) group: volume of 18 mL 0.25% bupivacaine+2 mL normal saline was given in the block. In (magnesium) group: volume of 18 mL 0.25% bupivacaine+1.5 mL MgSO4 (150 mg)+0.5 mL normal saline was given. They found that postoperative VAS for pain measurement was lower in group of magnesium in comparison to LA group at 4, 6, 18 and 24 hours with $P < 0.05$. Duration of analgesia was prolonged significantly in magnesium group when compared to LA group with $P < 0.001$. Decrease in the total dose of rescue analgesic was also noticed in group of magnesium in comparison to the other group with $P < 0.001$.

El Sherif et al. [13] in their work explored the analgesic effect of bupivacaine plus morphine in SAPB on 40 females participants planned to have MRM. Two groups were allocated: control (group C): received 20 ml bupivacaine hydrochloride 0.25% in SAPB US-guided and morphine (group M): received 10 mg morphine sulfate added to bupivacaine 0.25% (the same volume 20 ml). Both VAS at rest and with movement were significantly higher in group C more than in group M (with $P < 0.001$ and ≤0.003, respectively). Timing for the first request of rescue analgesia was

Table 4. Postoperative nausea and vomiting, complication and patient satisfaction in both groups.

	B group		BM group		
	No	%	No	%	P value
PONV score					
0	14	35	22	55	0.021*
1	16	40	18	45	
2	10	25	0	0	
Antiemetic ondansetron	5	12.5	3	7.5	0.106 N.S.
Complication and side effect					
Hematoma	2	5.0	2	5.0	1.00 N.S.
Hypotension	0	0.0	0	0.0	
Respiratory depression	0	0.0	0	0.0	
Patient satisfaction					
Very unsatisfied	11	27.5	0	0	0.001*
Unsatisfied	7	17.5	8	20	
Neutral	12	30	14	35	
Satisfied	10	25	9	22.5	
Very satisfied	0	0	9	22.5	

Data are presented as range, mean ± SD or No. (%)
* P ≤ 0.05 is significant.

after 8.5 hours in group C versus 20 hours in group M (P = 0.005). A median dose of acetaminophen consumption was 2 g in group C compared to 1 g in group M with P value = 0.006.

In a study by Lee and colleagues [25], magnesium sulfate was added to bupivacaine in interscalene block and its effect on postoperative pain was investigated. They found prolongation of the block in magnesium sulfate group with reduction in postoperative pain. Similar results were also concluded in a blinded, randomized, controlled trial, which was done by Al-Refaey et al. in which magnesium sulfate was added to bupivacaine in transversus abdominis plane block. [18]

In previous research studies, higher doses of magnesium sulfate of more than 200 mg were added to local anaesthetic and investigated to produce its effect, for example, Ibrahim and colleague [26] in their study did Pecs block and 500 mg magnesium was added to local anaesthetic and they found an increase in the analgesic duration to more than 9 hours.

In this work-study, the dose of magnesium sulfate used was 150 mg, and Gunduz and colleagues [27] in their work did the same, and they found that dose of 150 mg of magnesium sulfate as adjuvant to local anesthetic drugs provided significant elongation of the timing of motor and sensory blocks, without causing nerve toxicity or any side effects.

Therefore, based the work in this study, we concluded that 150 mg magnesium sulfate was sufficient to cause prolongation of analgesic duration with less requirement to rescue analgesic and better satisfaction scores and low percentage of PONV.

5 Conclusion

In this clinical research study, the adding effect of magnesium sulfate to bupivacaine during SAPB resulted in better postoperative analgesia with decreased pain scores. In addition, there was prolongation of motor and sensory block in addition to decrease in postoperative rescue analgesia needed with reduction in PONV. All that increased the patient satisfaction after surgery.

Disclosure statement

No potential conflict of interest was reported by the authors.

Study registration

At ClinicalTrials.gov: NCT04429893 (IRB No.: 00012098).

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